REMARKS

No extension of time is believed to be needed in connection with the filing of this paper. However, if an extension is deemed to be needed, please consider this paper to be a request for such extension and deduct any required fee from deposit account 10-1205/BECK:001.

Oath/Declaration

Objection has been raised that no mailing address is given for Marianne Winning. A new declaration is submitted herewith which overcomes this objection.

Claim rejections – 35 USC § 103

Claims 1, 3-11, 19-26, and 33-48 stand rejected under 35 USC § 103(a) as being unpatentable over Giagau et al (properly Glagau et al – DE 10206995) in view of Runge et al (WO 99/57242 / US 7037708) and Bakulesh et al (GB 2323532).

Glagau et al is said to teach a two-part micronutrient product which may be formulated as a multi-component single tablet and this is said to be taught at page 5, 4th paragraph – referring to a machine translation text). We submit that this is not the effect of the said disclosure and that the actual disclosure has been misunderstood or misrepresented by the Examiner.

The passage in question reads:

'Preferably, the Probiotika contained micro nutrient combination product of comprising at least two products with different composition is present in the form of 0 to 10 tablets, preferably 1 to 5 tablets, 0 to 10 capsules, preferably 1 to 5 capsules, 0 to 5 solutions, preferably 1 to 2 solutions and/or 0 to 5 granulates, preferably 1 to 3 granulates'.

The Examiner's interpretation of this is that all of the ingredients are disclosed to be present in, for instance, 1 to 10 tablets, and hence in one tablet.

We submit that this is a wrong reading of the sense of the passage taken as a coherent whole.

It is useful to consider what the passage means when it says that the combination product may comprise from 0 to 10 tablets. Clearly, it cannot be saying that the ingredients are all present in 0 tablet.

What is being said is that one can freely choose to employ tablets, capsules, solutions and granules in any combination in order to provide the combination of ingredients. That is to say, one can have 0 tablets, but then one needs capsules, solutions and/or granules.

By the same token, one can have 1 tablet, but it does not follow that this is all one has and that it contains all the ingredients, because it can be combined with any number of capsules, solutions and/or granules. So where 1 tablet is present, the ingredients of the total combination product may be split between that tablet and the remaining formulation forms.

This is fully in line with the overall teaching of Glagau et al, as we have explained it in our previous response of 19th January 2010. Glagau et al recognises the problems of putting both the micro-organisms and nutritionally active materials into the same formulation (e.g. tablet) and handles this by providing separate formulations for the micro-organisms and for the nutritionally active ingredients. Together, these separate formulations constitute the combination product of Glagau et al.

Given this overall teaching, it would indeed be odd if Glagau et al in the cited paragraph truly taught putting all the ingredients into one tablet.

At page 3, paragraph 4, Glagau et al states its invention at its broadest as follows:

'This object becomes by a formulated Probiotika contained micro nutrient combination product dissolved optimised regarding its ingredients, which covers at least two product portions with different composition, whereby a first portion covers Probiotika as effective ingredients and a second portion as effective ingredients Prebiotika and/or trace elements....'

At the top of page 5 of the translation, Glagau et al reads:

'The Probiotika according to the invention covers contained micro-nutrient combination product at least a separate first product of comprising as effective ingredients per bio tables cultures, ...; and at least a second separate present product comprising as effective ingredients vitamin A.....'

All the presently cited passage is saying is that these separate portions may take the form of separate tablets, separate capsules, separate solutions, or separate granulates, or combinations of these kinds of formulations. But nothing here suggests that you need not have a minimum of two separate portions, be they two tablets or one tablet with one granulate.

Any interpretation of the passage must make equal sense of the use of 0 and of the use of 1, and given the structure of the passage, these figures should be understandable on the same basis as one another.

The Examiner's contention that the passage described putting all the ingredients into one tablet falls down because it would imply that the passage equally describes putting all the ingredients into zero tablets. That would be a nonsense. If the reference to zero tablets means that one has in that case to use another formulation instead, then the reference to one tablet equally should imply the use of at least one other formulation type, given the overall teaching of at least two separate portions.

We submit that the Examiner's analysis of the obviousness issue falls down fundamentally at this point. The Examiner's analysis is based on the assertion that Glagau et al discloses a single tablet, albeit not zoned. This we submit is clearly wrong.

However, even if it were true, the objection would be unsustainable. Bakuleh et al is cited for disclosing a two zone tablet. It discloses compositions containing micro-organisms in one zone and antibiotics in a separate zone. The Examiner has not pointed out any disclosure of the presence of nutritionally active ingredients in the second zone. Leaving that aside, it is acknowledged by the Examiner that no water content or water activity is disclosed. The assertions regarding stability in Bakuleh et al are unsupported by any tests or data and seem lacking in credibility. For instance, it is asserted at page 22, that a liquid formulation containing micro-organisms and antibiotic is 'stable' for up to 7 days. Common sense would suggest that the micro-organism would not withstand the presence in solution of agents such as penicillin for that period.

However, the essential point is that nothing is taught in either Glagau et al or Bakuleh et al as to the water content and water activity characterising the present invention.

The Examiner relies in this connection on Runge et al, which teaches water content and water activity for a composition containing micro-organisms in the absence of nutritionally active ingredients.

The Examiner suggests that it would have been obvious to apply the formulation methods of Runge et al in respect of water content and water activity to the two zone compositions of Glagau et al.

The introduction to the Applicant's specification (page 1, para 1) explains that the invention addresses problems associated with the formulation of probiotic micro-organisms with other nutritionally active materials such as vitamins, minerals, carbohydrates, proteins, co-enzymes, enzymes, plant extracts, trace elements and/or fats. As explained there, many probiotic organisms are quite stable when kept by themselves in dried form.

What is shown in Runge et al is in accordance with this acknowledged state of the art. That is to say Runge et al discloses dried formulations in which micro-organisms are kept in the absence of the recited nutritionally active materials and the formulations are asserted to be such that the micro-organisms remain active for a prolonged period.

If one looks at the spray dried powders produced in the Examples in Runge et al, one sees this situation. The organisms are mixed with non-deleterious ingredients in Examples S1-S6 and spray dried powders are made. These are compacted into compacted starter culture preparations in the Formulation Example at column 18, again without addition of nutritionally active materials. Since such materials are absent, it is unsurprising that the micro-organisms should remain viable on storage.

The skilled reader learns nothing however from this in connection with how to store probiotic micro-organisms in the presence of such nutritionally active materials. In particular, the skilled reader does not learn that the water content and water activity disclosed in Runge et al is relevant to the problem of storage of probiotic micro-organisms in the presence of such nutritionally active materials.

Attempts have been made in the art to co-formulate probiotic micro-organisms with other nutritionally active ingredients, as acknowledged in the introduction (see especially US6254886 – Fusca et al). However, this led to a perceived need for extreme drying of the ingredients, beyond the level permitted by the Applicant's claims. A skilled reader familiar with that practice reading Glagau et al (and on the hypothesis that Glagau et al somehow does teach co-formulation - which is not accepted) with Bakuleh et al and Runge et al would suppose that extreme drying would be needed in a formulation based on such a combination also. The skilled reader would not be persuaded by reading Runge et al that this would not be the case. Although Runge et al teaches less than extreme levels of drying, that is in the context of a spray dried powder or compacted starter culture in which nutritionally active ingredients are avoided. The skilled person would not learn from the teaching of Runge et al that extreme drying would not be a necessity in a two part tablet formulation containing both probiotic micro-organisms and other nutritionally active ingredients as it is specifically taught to be in Fusca et al.

Should the skilled reader for some reason contemplate what would be the outcome of putting other nutritionally active ingredients into separate zone in the formulations of Runge et al (keeping the suggested levels of water content and water activity), the skilled reader could not have a reasonable expectation of success in maintaining the ability of the probiotic micro-organisms to withstand long term storage based on these teachings. The reasonable expectation would have been that the relatively high water content of such a product would facilitate the action of the 'other nutritionally active ingredients' in adversely affecting the micro-organisms and nothing in either of the two references Glagau et al and Bakuleh et al would suggest otherwise.

However, the point is moot in that Glagau et al does not actually teach a composition in the form of a single tablet as alleged.

The rejected claims are not obvious over the cited combination of art.

The other prior art relied on by the Examiner in rejecting Claims 2, 32 and 50 add nothing to support the erroneous rejection discussed in detail above. The novel and inventive features of claim 1 render these rejected claims inventive also.

The Examiner's response to previous arguments

The Examiner has responded to our argument that Runge et al's teaching is limited to do not contain deleterious ingredients and does not teach that its water activity and content conditions are relevant to the problem of storing micro-organisms in the presence of deleterious ingredients. The Examiner's response asserts that 'As long as the optimum water content and water activity are disclosed as being beneficial for a dried probiotic-containing composition one of ordinary skill in the art would have sufficient motivation and reasonable expectation of success to apply this teaching to all dried compositions that contain probiotics.' We respectfully submit that this assertion lacks any logical basis.

Given that the skilled person knows (e.g. Fusca et al) that the stable storage of micro-organisms in the presence of deleterious ingredients is a different and more severe problem than the storage of the organisms in the absence of those ingredients, there is no logical basis for the skilled person to assume that conditions taught to be suitable for storage in the absence of deleterious ingredients will also work in the presence of such ingredients.

The Examiner's second reason for rejecting our arguments was that Glagau et al explicitly teaches one tablet containing all the ingredients. This has been fully answered above.

In short, neither of the Examiner's reasons for rejecting our previous arguments holds water. The objections should be withdrawn.

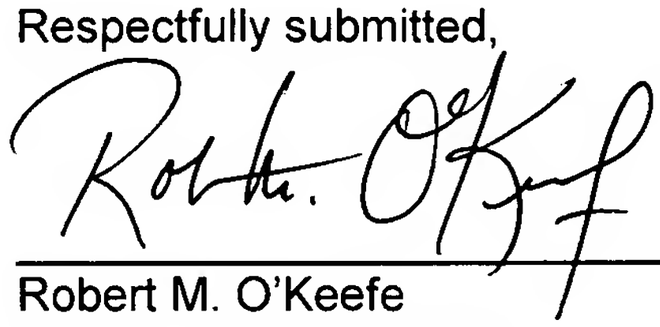
CONCLUSION

In view of the foregoing, it is submitted that the claims are in condition for allowance. Accordingly, favorable reconsideration and Notice of Allowance are courteously solicited.

Should any fees under 37 CRF 1.16-1.21 be required for any reason relating to the enclosed materials, the Commissioner is authorized to deduct such fees from Deposit Account No. 10-1205/BECK:001. The examiner is invited to contact the undersigned at the phone number indicated below with any questions or comments, or to otherwise facilitate expeditious and compact prosecution of the application.

If the claims are allowed, applicant respectfully requests that any appropriate claims that are currently withdrawn be rejoined into the application.

Respectfully submitted,



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